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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,013	01/12/2001	Masaaki Terada	0020-4769P	4777

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EXAMINER	
CHEN, SHIN LIN	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/701,013	TERADA ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *14 August 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): 35 U.S.C. 103(a) rejection of claims 34-36.

4. ☒ Newly proposed or amended claim(s) *37* would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *34-37*.

   Claim(s) objected to: *None*.

   Claim(s) rejected: *30-33*.

   Claim(s) withdrawn from consideration: *None*.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☒ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

S. Chen

Shin-Lin Chen
Primary Examiner
Art Unit: 1632

Continuation of 5. does NOT place the application in condition for allowance because: Regarding the 103(a) rejection of claims 30-33, applicants argue that the combination of the cited reference is a hindsight reconstruction and the chemical and physical properties of proteins and nucleic acids are very different (amendment, p. 6-7). This is not found persuasive because of the reasons of record. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Bonadio teaches a composition comprising a nucleic acid segment in association with a structural bone-compatible matrix, such as a collagen preparation for transferring the nucleic acid segment into bone progenitor cells located within bone progenitor tissue and Fujioka teaches preparation of a controlled release formulation comprising an active ingredient, such as protein or peptide and a collagen, such as an atelocollagen, and said formulation can release the active ingredient over a long period of time for increased therapeutic effects of the active ingredient. Collagen was known to provide stable gene preparation for efficient gene transfer,and atelocollagen is used for controlled relase formulation of active ingredients as taught by Fujioka. Although Bonadio does not teach using atelocollagen and the chemical and physical properties of proteins and nucleic acids are different, however, both collagen an atelocollagen are used to stabilize active ingredients, either proteins or nucleicd acids, and further, atelocollagen is a digested product of collagen. Therefore, one of ordinary skill in the art would have been motivated to substitute collagen as taught by Bonadio with atelocollagen as taught by Fujioka for stable gene preparation. Applicants argue that the amount of the amino acids used by Fujioka are larger than the amount used in the present invention (amendment, p. 7). This is not found persuasive because of the reasons of record and that the claimed invention does not specify a specific concentration of the amino acids used and adjusting the concentration of the amino acids used for optimization of reuslt would be obvious to one of ordinary skill in the art. Applicants argue that collagen is insoluble and atelocollagen is soluble and Bonadio suggests that the sustained release formulation should be insoluble (amendment, p. 7-8). This i not found persuasive because of the reasons of record and the reasons set forth above. Bonadio suggests the best matrices should be capable of being resorbed into the body but does not suggest the matrices should be insoluble. Further, it is unclear what "soluble" means by applicants. The term "soluble" can mean being soluble to water or soluble to organic solvents, such as acidic or basic solvents It is believed that both collagen and atelocollagen are insoluble to water. therefore, claims 30-33 remain rejected under 35 U.S.C. 103(a)